

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: PROTON-PUMP INHIBITOR
PRODUCTS LIABILITY LITIGATION**

**2:17-MD-2789 (CCC)(LDW)
(MDL 2789)**

**This Document Relates to:
All Actions**

Judge Claire C. Cecchi

(PROPOSED) ORDER

Upon consideration of the Report and Recommendation of Special Master Ellen Reisman regarding *Daubert* Motions (“Report and Recommendation”), any objections thereto, and the entire record herein, it is this ____ day of _____, 2022:

- 1) ORDERED that the Court overrules all objections to the Report and Recommendation and adopts the Report and Recommendation in its entirety as the decision of the Court;
- 2) ORDERED, as to all six Bellwether Trial Cases, that Plaintiffs’ Omnibus *Daubert* Motion to Exclude Defense Experts be and hereby is DENIED as to the testimony of Dr. Marianne Mann;
- 3) ORDERED, as to all six Bellwether Trial Cases, that Plaintiffs’ Omnibus *Daubert* Motion to Exclude Defense Experts be and hereby is GRANTED IN PART and DENIED IN PART as to Dr. Janice Lansita, as follows:

a. The motion is GRANTED to the extent that it seeks to exclude Dr. Lansita from offering the following opinions:

- i. The pathological criterion or significance of CPN to humans (per stipulation by the Parties);
- ii. The historical cost of bringing Nexium or Prilosec to market (per stipulation by the Parties);
- iii. The cost of bringing a drug to market generally;
- iv. Whether PPIs would be approved by the FDA today;

b. The motion is otherwise DENIED, including but not limited to, as to Dr. Lansita's testimony as to the following:

- i. Her opinions concerning the nonclinical studies relating to PPIs that she reviewed; and
- ii. The sufficiency of the nonclinical studies relating to PPIs to support FDA approval;

4) ORDERED, as to all six Bellwether Trial Cases, that Plaintiffs' Omnibus *Daubert* Motion to Exclude Defense Experts be and hereby is DENIED as to the testimony of Dr. Robert Gibbons;

5) ORDERED, as to the *Rieder* and *Bales* cases, that Plaintiffs' Omnibus *Daubert* Motion to Exclude Defense Experts be and hereby is DENIED as to the testimony of Dr. Rajat Deo and that, to avoid any jury confusion, the

juries in the *Rieder* and *Bales* trials will be instructed in connection with Dr. Deo's testimony that he was not asked to and did not consider or form any opinions as to whether Plaintiff Rieder's or Plaintiff Bales's use of PPIs was a cause of either of their CKD;

6) ORDERED, as to the *Rieder* case, that Plaintiffs' Omnibus *Daubert* Motion to Exclude Defense Experts be and hereby is GRANTED as to the testimony of Dr. Caren Palese;

7) ORDERED, as to all six Bellwether Trial Cases, that Defendant AstraZeneca's Motion to Exclude Opinion Testimony from Dr. David Ross Under Federal Rule of Evidence 702 and, as to the *Bales* case, Defendant Takeda's Motion to Exclude Testimony of Dr. David Ross, be and they hereby are DENIED, except as follows;

- a. The motion is GRANTED in part to the extent that Dr. Ross shall be precluded from testifying as to FDA's level of understanding of the difference between ATIN and CTIN, except that if AstraZeneca, which elicited such testimony in Dr. Ross's deposition, opens the door by seeking to use his deposition testimony on this topic on cross-examination or to elicit it again at trial, such testimony shall be permitted;

b. The motion is GRANTED in part to the extent that any testimony by Dr. Ross about FDA staffing and resources in periods after the conclusion of his service at FDA shall not be permitted and any such testimony shall be limited to his personal experience during his tenure at FDA or upon objective evidence of such issues;

- 8) ORDERED, as to all six Bellwether Trial Cases, that Defendants AstraZeneca's and Takeda's Motions to Exclude Opinion Testimony from Dr. Martin Wells Under Federal Rule of Evidence 702 be and hereby are GRANTED to the extent they seek to exclude Dr. Wells from offering an opinion on general causation that PPIs cause CKD or are harmful to the kidneys (per stipulation by the Parties) and are DENIED if evidence of data provided to PRAC or PRAC's analysis or conclusions is introduced at trial.
- 9) ORDERED that, as to all six Bellwether Trial Cases, Defendant AstraZeneca's Motions to Exclude Opinion Testimony from Plaintiffs' General Causation Experts Under Federal Rule of Evidence 702 be and hereby are DENIED as to the testimony of Dr. David Charytan.
- 10) ORDERED that, as to the *Bales*, *Lee*, *Nelson*, *Foster*, and *Rieder* cases, Defendant AstraZeneca's Motions to Exclude Opinion Testimony from Plaintiffs' General Causation Experts Under Federal Rule of Evidence 702

be and hereby are GRANTED IN PART and DENIED IN PART as to the testimony of Dr. Wajahat Mehal, as follows:

a. The motions are GRANTED to the extent that they seek to exclude Dr. Mehal from offering the following opinions:

- i. The adequacy of labeling of PPIs (per stipulation by the Parties);
- ii. Medical marketing and its impact on sales of PPIs; and
- iii. The impact of the Montreal definition of GERD in any case where the plaintiff underwent medical testing that specifically confirmed a GERD diagnosis;

b. The motions are otherwise DENIED, including but not limited to, with respect to Dr. Mehal's general causation opinions.

11) ORDERED that, as to the *Rieder* case, Defendant AstraZeneca's Motion to Exclude Opinion Testimony from Plaintiffs' Specific Causation Experts Under Federal Rule of Evidence 702 be and hereby is DENIED as to the testimony of Dr. Derek Fine;

12) ORDERED, as to all six Bellwether Trial Cases, that Defendant AstraZeneca's Motions to Disqualify Dr. Gilbert Moeckel be and hereby are DENIED;

- 13) ORDERED that, as to all six Bellwether Trial Cases, Defendant AstraZeneca's Motions to Exclude Opinion Testimony from Dr. Gilbert Moeckel Under Federal Rule of Evidence 702 and, as to the *Bales* case, Defendant Takeda's Motion to Exclude Expert Testimony of Dr. Gilbert Moeckel be and they hereby are DENIED;
- 14) ORDERED that, as to all six Bellwether Trial Cases, to the extent the Parties have raised any arguments in their motions that are not specifically addressed in Special Master Reisman's R&R, such arguments be and hereby are rejected and the corresponding motions are DENIED to the extent that they rely on those rejected arguments.

Claire C. Checchi
United States District Judge